

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)

**CERTIFICATION OF ADAM M. SLATER IN SUPPORT OF  
PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE  
THE GENERAL CAUSATION OPINION OF STEPHEN S. HECHT, PH.D.**

ADAM M. SLATER, hereby certify as follows:

1. I am an attorney at law within the State of New Jersey and a partner with the law firm of Mazie Slater Katz & Freeman, LLC, and serve as Plaintiffs' Co-Lead Counsel. I am fully familiar with the facts and circumstances of these actions. I make this Certification in support of Plaintiffs' opposition to Defendants' motion to exclude the general causation opinion of Stephen S. Hecht, Ph.D.
2. Attached hereto as **Exhibit 1** is a true and accurate copy of Internal Agency for Research on Cancer, *Some N-Nitroso Compounds*, in *IARC Monogr. Eval. Carcinog. Risk Chem. Hum.*, 107, 152 (Lyon, Fr. 1978).
3. Attached hereto as **Exhibit 2** is a true and accurate copy of FDA, *FDA presents interim limits of nitrosamines in currently marketed ARBs* (Dec. 19, 2018), <https://tinyurl.com/4rkpdf5h>.
4. Attached hereto as **Exhibit 3** is a true and accurate copy of EPA, *N-Nitrosodimethylamine*, <https://tinyurl.com/9krh69u9>.

5. Attached hereto as **Exhibit 4** is a true and accurate copy of EPA, *N-Nitrosodiethylamine*, <https://tinyurl.com/48y7nejw>.

6. Attached hereto as **Exhibit 5** is a true and accurate copy of the relevant excerpt of the USP, Summary, Highlights and Timeline of General Chapter <1469> Nitrosamine Impurities (July 20, 2018).

7. Attached hereto as **Exhibit 6** is a true and accurate copy of Liteplo & Meek, *Concise International Chemical Assessment Document 38 – N-Nitrosodimethylamine* (WHO 2002).

8. Attached hereto as **Exhibit 7** is a true and accurate copy of Wang, Cheng, Villalta, Hecht, *Development of liquid chromatography electrospray ionization tandem mass spectrometry methods for analysis of DNA adducts of formaldehyde and their application to rats treated with N-nitrosodimethylamine or 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone*, CHEM. RES. TOXICOL. 20, 1141-1148 (2007).

9. Attached hereto as **Exhibit 8** is a true and accurate copy of Yamazaki, Inui, Yun, Guengerich, & Shimada, *Cytochrome P450 2E1 and 2A6 enzymes as major catalysts for metabolic activation of N-nitrosoalkylamines and tobacco-related nitrosamines in human liver microsomes*, CARCINOGENESIS 13, 1789, 1792 (1992).

10. Attached hereto as **Exhibit 9** is a true and accurate copy of Herron & Shank, *Methylated purines in human liver DNA after probable dimethylnitrosamine poisoning*, CANCER RESEARCH 40, 3116-3117 (1980).

11. Attached hereto as **Exhibit 10** is a true and accurate copy of Archer, *Mechanisms of action of N-nitroso compounds*, CANCER SURVEYS 8, 241-250 (1989).

12. Attached hereto as **Exhibit 11** is a true and accurate copy of Anderson, Souliotis, Chhabra, Moskal, Harbaugh, and Kyrtopoulos, *N-nitrosodimethylamine-derived O(6)-methylguanine in DNA of monkey gastrointestinal and urogenital organs and enhancement by ethanol*, INT. J. CANCER 66, 130-4 (Mar. 1996).

13. Attached hereto as **Exhibit 12** is a true and accurate copy of SOLCO00024226 (ZHP 129).

14. Attached hereto as **Exhibit 13** is a true and accurate copy of the relevant excerpt of PRINSTONO0075850.

15. Attached hereto as **Exhibit 14** is a true and accurate copy of the relevant excerpt of the April 22, 2021 deposition transcript of Min Li.

16. Attached hereto as **Exhibit 15** is a true and accurate copy of *Player v. Motiva Enterprises LLC*, No. Civ. 02–3216(RBK), 2006 WL 166452 (D.N.J. January 20, 2006).

17. Attached hereto as **Exhibit 16** is a true and accurate copy of the relevant excerpt of the April 30, 2021 deposition transcript of B.V. Ramarao.

18. Attached hereto as **Exhibit 17** is a true and accurate copy of Dr. Stephen Hecht's CV.

19. Attached hereto as **Exhibit 18** is a true and accurate copy of *Geiss v. Target Corp.*, No. 09–2208 (RBK/KMW), 2013 WL 4675377 (D.N.J. 2013).

20. Attached hereto as **Exhibit 19** is a true and accurate copy of Knekt, Järvinen, Dich, & Hakulinen, *Risk Of Colorectal Cancer And Other Gastro-Intestinal Cancers After Exposure to Nitrate, Nitrite and N-Nitroso Compounds: A Follow-Up Study*, INT. J. CANCER 80, 852-856, at 855 (1999).

21. Attached hereto as **Exhibit 20** is a true and accurate copy of *In re Xarelto (Rivaroxaban) Prod. Liab. Litig.*, Case No. 2:14-MD-02592, Doc 6198, 2017 WL 1352860 (E.D. La, Apr. 13, 2017).

22. Attached hereto as **Exhibit 21** is a true and accurate copy of Song, Wu, & Guan, *Dietary Nitrates, Nitrites, and Nitrosamines Intake and the Risk of Gastric Cancer: A Meta-Analysis*, NUTRIENTS 7, 9872-95, at 9892-9893 (2015).

23. Attached hereto as **Exhibit 22** is a true and accurate copy of Peto, Gray, Brantom, & Grasso, *Effects on 4080 rats of chronic ingestion of N-nitrosodiethylamine or N-nitrosodimethylamine: a detailed dose-response study*, CANCER RES. 51, 6415-6451 (1991).

24. Attached hereto as **Exhibit 23** is a true and accurate copy of the relevant excerpt of the May 7, 2021 deposition transcript of Lance Molnar.

25. Attached hereto as **Exhibit 24** is a true and accurate copy of Pottegård, Kristensen, Ernst, Johansen, Quartarolo, & Hallas, *Use of N-nitrosodimethylamine (NDMA) contaminated valsartan products and risk of cancer: Danish nationwide cohort study*, B.M.J. 362., 1 (2018).

26. Attached hereto as **Exhibit 25** is a true and accurate copy of Gomm, Röthlein, Schüssel, Brückner, Schröder, Hess, Frötschl, Broich, & Haenisch, *N-Nitrosodimethylamine-Contaminated Valsartan and the Risk of Cancer—A Longitudinal Cohort Study Based on German Health Insurance Data*, DTSCH. ARZTEBL INT. 118, 358, 359 (2021).

27. Attached hereto as **Exhibit 26** is a true and accurate copy of FDA, *Control of Nitrosamine Impurities in Human Drugs: Guidance for Industry*, p. 1 (Feb. 2021), <https://tinyurl.com/2p8uxyyb>.

28. Attached hereto as **Exhibit 27** is a true and accurate copy of the relevant excerpt of the Report of Dr. George Johnson.

29. Attached hereto as **Exhibit 28** is a true and accurate copy of *Glynn v. Merck Sharp & Dohme Corp.*, Nos. 11–5304, 08–08, 2013 WL 1558690 (D.N.J. Apr. 10, 2013).

**MAZIE SLATER KATZ & FREEMAN, LLC**  
Attorneys for Plaintiffs

By: /s/ Adam M. Slater

Dated: December 1, 2021